IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SYSMEX CORPORATION and SYSMEX AMERICA, INC. Plaintiffs, v. BECKMAN COULTER, INC., Defendant.	)	C. A. No.: 19-1642-JFB-CJB **JURY TRIAL DEMANDED**

DEFENDANT BECKMAN COULTER, INC.'S
OBJECTIONS TO THE REPORT AND RECOMMENDATION
GRANTING PARTIAL SUMMARY JUDGMENT AS TO THE ADVIA 2120 (D.I. 507)

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I. INTRODUCTION

Pursuant to Fed. R. Civ. P 72(b)(3), Beckman Coulter, Inc. ("BCI") respectfully objects to Magistrate Judge Burke's May 20, 2022 Report and Recommendation (D.I. 507, "R&R"). The R&R would grant Sysmex Corporation and Sysmex America, Inc.'s (collectively, "Sysmex") motion for partial summary judgment (D.I. 407), which sought summary judgment of no invalidity as to the "Advia 2120" hematology analyzer. Because of a new representation by Sysmex in its reply brief, the Court should clarify that the R&R applies only to the Advia 2120 analyzer, and not the Advia 120 analyzer. The Court should also modify the R&R to the extent it ignores relevant facts and impermissibly weighs the evidence in favor of Sysmex. When all relevant evidence is considered and interpreted in the light most favorable to the non-movant, BCI submits that there is a genuine issue of material fact as to whether the Advia 2120 invalidates the claims of the Asserted Patents. These issues should be resolved at trial.

II. LEGAL STANDARD

When reviewing an R&R on a dispositive matter like summary judgment, the Court conducts a *de novo* review. *See* 28 U.S.C. § 636(b)(1); Fed. R. Civ. P 72(b)(3). District courts may accept, reject, or modify the recommendations, and also receive further evidence. *Masimo Corp. v. Philips Elecs. N.A. Corp.*, 62 F. Supp. 3d 368, 379 (D. Del. 2014).

III. ARGUMENT

A. The R&R Grants Summary Judgment for the Advia 2120 Only

The R&R allows summary judgment regarding the Advia 2120 analyzer, on the basis that there are purportedly insufficient facts to support a finding of invalidity. (D.I. 507 ("[T]here is insufficient evidence from which a reasonable fact finder could conclude by clear and convincing evidence that the *Advia 2120* that may have been on sale in the U.S. prior to the critical date actually anticipates or renders obvious the asserted claims at issue.") (emphasis added).) The R&R

does not reach a similar conclusion with respect to a predecessor product to the Advia 2120, namely, the Advia 120 analyzer. Therefore, the R&R should be clarified to indicate that it did not decide summary judgment as to the Advia 120 analyzer.

In its pending Motion in *Limine* No. 3, Sysmex itself has specifically acknowledged that the Advia 120 is separate and distinct from the Advia 2120 in its counting of BCI's Advia 2120 prior art invalidity grounds as compared to BCI's Advia 120 prior art invalidity grounds. (Ex. 1 at 2–3 ("BCI contends that 17 of the Asserted Claims are anticipated by the Advia 120 device . . . Thus, any argument that the Advia 2120 anticipates the asserted claims or renders them obvious is a completely separate and additional argument from BCI's argument that the Advia 120 anticipates the asserted claims or renders them obvious").) Sysmex has further made clear that its motion *in limine* is limited only to evidence regarding the Advia 2120. (Ex. 2 (clarifying Sysmex's Motion is directed to the "Advia 2120, *not the Advia 120*.") (emphasis added).) Moreover, Sysmex's summary judgment motion was directed to "Dismissal of Invalidity Based on Advia2120 Product," not the Advia 120. Consequently, the Advia 120 remains part of BCI's defenses for presentation at trial.

Although its holding is limited to Advia 2120, language in the R&R makes unnecessary implications regarding BCI's other invalidity positions. The R&R states that its expert "Mr. Roche *never* opined as to how the *Advia 120* reads on the asserted claims." (D.I. 507 (emphases added).) This is incorrect and appears to be based on a misrepresentation advanced for the first time in Sysmex's summary judgment reply brief. (D.I. 436 at 11 ("BCI has failed to provide a limitation by limitation analysis showing how the Asserted Claims allegedly read on the Advia 120").) Although BCI has argued and maintains that the Advia 120 and Advia 2120 are identical with respect to the asserted patent claims, Mr. Roche nevertheless *does* explain on a "limitation by

limitation" basis how the Advia 120 anticipates and/or renders obvious those claims. This was done in addition to his analysis of the Advia 2120, as detailed in the claim charts submitted with his opening expert report (D.I. 408, Ex. 11 at Ex G, H.) For example, Mr. Roche opines:

Claim 1 [CL2] a plurality of detectors each configured to sense cells in a sample,	The **Advia2120** has a "[p]erox optical assembly." **Advia-OG**, 7-8. The **Advia2120** also has a "laser optical assembly." **K003796**, 47;**Advia-OG**, 8. Through photodiodes, "[t]he perox optical assembly measures scattering and absorption of a tungsten light beam as it passes through a stream of prepared white blood cells in a flowcell." **Advia-OG**, 7. Representations of the perox optical assembly and RBC optical assembly are provided below (**Advia-OG**, 7-8): ••• Similarly, the **Advia120** has a "[p]erox optical assembly." **K003796**, 47. The **Advia120** also has an "RBC optical assembly." **K003796,** 47. "[W]hite cells are counted using 2 angle laser light scattering signals associated with the shape end complexity of cell nuclei" and "[t]he RBC count is derived from the RBC/Plt channel of the system where low and high angle laser light scattering properties are used to count and classify red cells based on volume and hemoglobin concentration." **K003796**, 15.

(Ex. G at 1–3; *see also* Ex. G at 1–37; Ex. H at 1–38.) Those same charts were submitted by Sysmex into the summary judgment record.[1] The R&R overlooks Mr. Roche's opinions regarding the Advia 120. The R&R's commentary on the Advia 120 should be considered as to dicta. *See United States v. Salahuddin*, 765 F.3d 329, 339 n. 2 (3d Cir. 2014) (defining dicta as a "statement in a judicial opinion that could have been deleted without seriously impairing the analytical foundations of the holding —that, being peripheral, may not have received the full and careful consideration of the court that uttered it"). The Court should reject any unintended characterization of BCI's theories in the R&R in a manner that is inconsistent with the record in this case. *See Kirtsaeng v. John Wiley & Sons, Inc*., 568 U.S. 519, 548 (2013) ("[W]e are not necessarily bound by dicta should more complete argument demonstrate that the dicta is not correct."); *McGurl v. Trucking Emps. of N. Jersey Welfare Fund, Inc*., 124 F.3d 471, 484 (3d Cir. 1997) (holding that dicta is non-binding).

[1] BCI re-submits Exhibits G and H from Mr. Roche's report here with highlighting.

B. The R&R Erred in Recommending Summary Judgment on the Advia 2120

The R&R expressly conditions its grant of summary judgment on four grounds: (1) it is improper to consider Dr. Zelmanovic's declaration submitted with BCI's summary judgment opposition brief (D.I. 431, Ex. 63); (2) Mr. Roche's reference to his personal experience is too vague to support his invalidity opinions; (3) there is insufficient evidence to infer the Advia 2120 is the same as the Advia 120; and (4) there is insufficient evidence to infer that the Advia-OG describes an Advia product prior to February 2007.[2] Each of these grounds is based on a misapplication of law and/or an improper determination of the facts on summary judgment.

1. Dr. Zelmanovic's Declaration Should Not be Excluded

The R&R should have considered Dr. Zelmanovic's declaration. The R&R acknowledges that Dr. Zelmanovic was identified to Sysmex as a source of information regarding the operation of the prior art Advia products through Mr. Roche's opening expert report on June 1, 2021. (D.I. 507; D.I. 430, Ex.41′ ¶ 226.) Yet, the R&R did not consider the declaration at summary judgment due to its purported findings of prejudice under the *Pennypack* factors.[3] This is clearly erroneous for at least two reasons.

First, the R&R's decision violates the well-established principle that declarations can be and should be considered on summary judgment. *See J.F. Feeser, Inc. v. Serv-A-Portion, Inc*., 909 F.2d 1524, 1542 (3d Cir. 1990) (finding that "hearsay evidence produced in an affidavit opposing summary judgment may be considered if the out-of-court declarant could later present the evidence through direct testimony"). Indeed, it is appropriate to evaluate a declaration for summary judgment purposes especially when the declarant is known to the opposing party. *See Alpek*

[2] Relevant excerpts of the Advia-OG were submitted in D.I. 432, Ex. 75.
[3] BCI understands that "*Pennypack*" in the R&R refers to *Meyers v. Pennypack Woods Home Ownership Assn*., 559 F.2d 894 (3d. Cir. 1977).

Polyester, S.A. v. Polymetrix, A.G., No. 2021-1706, 2021 WL 5974163, at *7 (Fed. Cir. Dec. 16, 2021) (denying motion to strike a declaration when the opposing party knew of the declarant and finding no harm even though the declarant was not identified in a Rule 26(e) disclosure); *see also Dasso Int'l, Inc. v. MOSO N. Am., Inc.*, No. CV 17-1574-RGA, 2021 WL 4427168, at *7 (D. Del. Sept. 27, 2021) (voluntary declaration was properly considered on summary judgment).

Second, it is undisputed that the parties did not address the *Pennypack* factors in their summary judgment briefs—Sysmex did not raise it. Nor did the parties discuss or reference *Pennypack* in any other paper with respect to the declaration. Nonetheless, the R&R raises and analyzes this issue without giving either party prior notice. Because the grant of summary judgment is based on a *sua sponte* application of *Pennypack*—which the parties had never briefed—the R&R should be rejected. *See Charles Mach. Works, Inc. v. Vermeer Mfg. Co., 723 F.3d 1376*, 1378–79 (Fed. Cir. 2013) (vacating grant of summary judgment because the non-movant "had insufficient notice that the summary judgment decision would include" certain accused products and the issue was not briefed); *Pei-Herng Hor v. Ching-Wu Chu*, 699 F.3d 1331, 1337 (Fed. Cir. 2012) ("[A]lthough a district court certainly has the discretion to *sua sponte* grant summary judgment, it nevertheless must afford the losing party notice").

Under these circumstances, the R&R should have considered Dr. Zelmanovic's statements when determining whether to grant Sysmex's motion. As the R&R notes, Sysmex was aware of Dr. Zelmanovic since June 2021. (D.I. 507.) Sysmex, either on its own or through Dr. Robinson, could have independently contacted Dr. Zelmanovic to confirm any information, or sought to take his deposition during summary judgment briefing. And given that BCI has now added Dr. Zelmanovic to its initial disclosures and identified him as a trial witness, Sysmex can hardly complain. *See J.F. Feeser*, 909 F.2d at 1542; *Alpek*, 2021 WL 5974163, at *7. (Ex. 3, 4.) Sysmex

has known of Dr. Zelmanovic's involvement for nearly a year, and has had his declaration for five months. The R&R, however, did not address these issues and should be modified, accordingly.

2. Mr. Roche's Personal Experience Should Not Be Discounted

Contrary to assertions made in the R&R, Mr. Roche does not merely refer to his experience and third-party conversations in order to support his invalidity opinions. Instead, Mr. Roche states that his opinions on the Advia 2120 are based on his extensive personal experience *as well as* his review of manuals and references and discussions with co-inventors of the Ornstein patent and other Advia 2120 developers. (D.I. 430, Ex. 41′ ¶ 226.) Mr. Roche also considered a prior art Harris article regarding the "multicenter trial on the Advia." (D.I. 432, Ex. 77 at 249:21–250:7.) Harris I, published in 2005, which describes the Advia 120 as "a well-established modern cell counter for blood and biological fluid analysis that is used in clinical laboratories worldwide." (D.I. 431, Ex. 68 at 62– 63.) Harris further describes the Advia 2120 as "recently introduced," and reports the results of an evaluation performed at six sites, including three in the United States. (*Id.* at 63.)

Considered together, this evidence provides more than an adequate basis for Mr. Roche to reach his conclusion that the Advia 2120 (and the Advia 120) products anticipate many of the asserted claims, and that such products were on sale and in use in the United States before February 2007. This is particularly true in light of the declaration of Dr. Zelmanovic (D.I. 431, Ex. 63), with whom Mr. Roche spoke in forming his opinions (D.I. 430, Ex. 41′ ¶ 226).

The R&R also makes credibility and fact determinations regarding Mr. Roche's "personal experience." This ought to be reserved for the jury. *See McCloskey v. Westfield Ins. Co.*, No. CV 15-6210, 2016 WL 6821900, at *4 (E.D. Pa. Nov. 18, 2016) (declining to grant summary judgment despite the allegation that the plaintiff's testimony is "too vague to be credited" because the court could not settle the issue "without impermissibly weighing the evidence and making credibility

determinations"); *Anderson v. Liberty Lobby,* Inc., 477 U.S. 242, 249 (1986) ("[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.").

3. The Record Shows the Advia 2120 and the Advia 120 to be Materially the Same

There are numerous issues of fact as to whether the Advia 2120 and Advia 120 are the same in all material respects. Sysmex itself has conceded that the Advia 2120 "system equals the Advia 120" and that Advia 2120 is merely a "re-launch[]" of the Advia 120. (D.I. 432, Ex. 85 at 336519; *see also* D.I. 431, Ex. 67 at 289900–01.) Sysmex also has confirmed that the Advia 2120 operated the same as the Advia 120 *with respect to body fluid analysis* during its efforts to develop its own body fluid mode for the XE-5000. (D.I. 431, Ex. 66 at 125160 (testing the instrument, "ADVIA120 CSF mode (or ADVIA 2120)").) Further, Mr. Roche relies on "operating manuals, marking materials, and journal articles" for the Advia 120 as well as his own personal experience in order to explain the functionality of the Advia 2120. (D.I. 430, Ex. 41′ ¶¶ 196, 226; D.I. 432, Ex. 77 at 249:21–250:7.) And Dr. Zelmanovic confirms from his experience as a Bayer scientist that the differences between the Advia 2120 and the Advia 120 are merely cosmetic. (D.I. 431, Ex. 63 ¶ 3.). The record at summary judgment contains ample support for a jury to reasonably infer that the Advia 2120 and Advia 120 operated in the same way with respect to the claim limitations.

The R&R wrongly sweeps aside this evidence by stating that certain facts set forth by BCI are too vague to support a claim of invalidity while dismissing other facts as "attorney arguments." The R&R again supplants the role of the jury by weighing the evidence and making credibility determinations. See *McCloskey,* 2016 WL 6821900, at *4; *U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345, 1351 (Fed. Cir. 2016) ("The District Court recognized this was conflicting evidence that went to the core of an inherent anticipation analysis, but concluded this evidence did

not preclude summary judgment . . . [D]isregarding this evidence, the District Court improperly made credibility determinations and weighed conflicting evidence").

The R&R inappropriately credits the opinions of Sysmex's expert, Dr. Robinson, over the opinions of Mr. Roche as to similarities between the Advia 120 and the Advia 2120. The R&R wrongly determines that Mr. Roche never "explained how the Advia 120 was similar or different from the Advia 2120" when Mr. Roche, in his opening report, characterizes his opinions as relating to the "Advia 120 / 2120 Analyzer." (D.I. 430, Ex. 41′ at 69.) The disagreement between Dr. Robinson and Mr. Roche over the issue of whether the Advia 120 is the same as the Advia 2120 presents a classic battle of the experts that the Court should not resolve at summary judgment. *See Evolved Wireless, LLC v. Apple, Inc*., No. CV 15-542-JFB-SRF, 2019 WL 831112, at *5 (D. Del. Feb. 21, 2019).

4. The Advia-OG Correctly Describes the Advia 2120 Before the Critical Date

BCI does not intend to submit the Advia-OG as prior art. Rather, the probative value of the Advia-OG lies in its detailed disclosure of the operation and functionality of the Advia 2120. Here, a triable issue of fact exists as to whether the Advia-OG accurately and reliably describes an Advia 2120 that was in use and/or on sale prior to the § 102 critical date of February 1, 2007. The evidence in the summary judgment record includes: (1) the similarity between the Advia-OG's description of the operation of the Advia 2120, (particularly the CSF Mode) and the descriptions of the CSF mode found in the earlier patent application Ornstein and the FDA K003796 (D.I. 432, Ex. 75 at 233407–09, Ex. 76 ¶¶ [0061], [0075]–[0076]; D.I. 431, Ex. 70 at 235124); (2) references in the Advia-OG to the predecessor "*ADVIA 120* Hematology System" (D.I. 432, Ex. 75 at BCID233407 (emphasis added)); (3) Dr. Zelmanovic's declaration that a 2010 version of Advia-OG in his possession accurately describes the operation of the CSF Mode on the Advia 2120 as it existed in 2005 (D.I. 432, Ex. 63 ¶11); and (4) the overlap between BCI's Advia-OG and the Dr.

Zelmanovic's version of the manual (*compare* D.I. 432, Ex. 63 at Ex. A at 9-36 to 9-38 *with* D.I. 432, Ex. 75 at 233407–09). Taken together, these facts are more than sufficient to support a reasonable inference that (1) there had been no material changes to the Advia 2120 from 2005 to 2010 and (2) the Advia-OG correctly details the functionality of the Advia product that existed before February 2007.

The R&R, nevertheless, determines that the Advia-OG is inapplicable because the Advia-OG was not published prior to 2007. According to the R&R, that the Advia-OG bears a copyright date of 2007 and a publication date of 2008 is "not enough to meet Defendant's burden to demonstrate what the contours of the device actually were as of January 2007 or earlier." But BCI presented documentary evidence such as Ornstein and K003796 not only to corroborate the disclosure in the Advia-OG, but also to show that the Advia-OG is a correct and reliable source of information regarding the operations of the Advia product before 2007. *See, e.g.*, *Move, Inc. v. Real Estate Alliance Ltd*., 221 F. Supp. 3d 1149, 1169 (C.D. Cal. 2016) (allowing user manual corroborating prior art was on sale before critical date). This evidence is supported by Dr. Zelmanovic. The R&R should have considered the totality of the evidence in a light most favorable to BCI. By not doing so, the R&R legally erred. *McCloskey,* 2016 WL 6821900, at *4; *U.S. Water,* 843 F.3d at 1351; *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 761 F.3d 1329, 1342 (Fed. Cir. 2014) (holding that the district court erred in discounting evidence for summary judgement purposes).

IV. CONCLUSION

For the foregoing reasons, BCI respectfully requests that the Court deny Sysmex's motion for partial summary judgment with respect to the Advia 2120.

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